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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT	PAPER NUMBER
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3735

NOTIFICATION DATE	DELIVERY MODE
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02/03/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/648,849	Applicant(s) GOODE ET AL.	
	Examiner CHRISTIAN JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 122, 192-207, 270-291, 293 and 332-342 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/2/10, 8/3/10</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 119-126,148-155,158-175,177-207,209-211,213-236,238-291,293-314 and 316-342.

Continuation of Disposition of Claims: Claims rejected are 119-121,123-126,148-155,158-175,177-191,199,209-211,213-236,238-269,294-314 and 316-331.

DETAILED ACTION

1. This Office Action is responsive to amendments filed on July 29th, 2010.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 160, 176, 191, 208, 212, 237, 258, 310, 315 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Claims 160, 176, 191, 208, and 310 recite a step of detecting transient non-glucose related signal artifact performed on the calibrated data stream. The specification fails to provide support for such a feature.

5. Claims 212, 237, 292, 315 recite high pass filtering. The specification fails to provide support for such a feature.

6. Claims 219-221, 241-243, 261-263, 319-321 recite discarding, replacing, or determining whether an estimated value is outside of a predetermined range. The specification fails to provide support for such a feature.

7. Claim 258 recites comparing the rate of change with a preselected value. The specification fails to provide support for such a feature.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 119-121, 123-126, 145-153, 155, 158-171, 173-175, 177-186, 188-191, 199, 209-211, 213-223, 227, 233-236, 238-245, 254-265, 294-303, 305-314, 316-323 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al. (US 2003/0050546) in view of Berner (USP #6,233,471).

10. As to claim 119-121, Desai teaches monitoring a data stream (Fig. 2), detecting signal artifacts ([0282]), and replacing the artifacts with estimated glucose values ([0013]) and outputting the one or more estimated values (Fig. 4B). While Desai does not teach the use of an amplitude, duration, or rate-of-change to detect the severity, Desai incorporates by reference the teachings of Berner for determining error associated criteria ([0282]). Berner teaches the use of amplitude, duration, and rate-of-change (col. 21 lines 10-53).

11. As to claims 123-126, 162-165, 177-180, 294-297, 306-307, Desai teaches applying one of a plurality of distinct signal estimation algorithm factors in response to the severity.

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12. As to claims 148, 166, 181, 216-218, 223, 233, 239-240, 245, 254, 259-260, 265, 298, 311, 317-318, 323, Desai teaches displaying the estimated values and the data stream (Fig. 4B).

13. As to claims 149, 167, 182, 209-210, 234-235, 255-256, 299, 312-313, Desai teaches filtering the data stream ([0125]).

14. As to claims 150, 168, 183, 211, 236, 257, 300, 314, Desai teaches raw data ([0081]).

15. As to claims 151-152, 169-170, 184-185, 301-302, Desai teaches the sensor types as claimed ([0100]).

16. As to claim 153, 171, 186, 303, Berner teaches monitoring amplitude noise (col. 21 lines 10-53).

17. As to claim 155, 173, 188, 305, Desai teaches the replacing is substantially continual (as monitoring is done continually).

18. As to claim 158, 174, 189, 220, 242, 262, 308, 320, Desai teaches discarding signal artifacts ([0148]).

19. As to claim 159-161, 175, 190-191, 309-310, Desai teaches calibrating data streams and detecting artifacts in the calibrated stream ([0050]).

20. As to claims 213-215, 238, 316, the above combination does not disclose expressly the detection of high frequency cycles, low amplitude noise, and measuring amplitudes of high frequency cycles. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect high frequency cycles, low amplitude noise, and measuring amplitudes of high

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frequency cycles because applicant has not disclosed that the detection of these parameters provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Berner's teachings to perform equally well with either the detection disclosed by Berner or those claimed by the applicant. As such, it would have been prima facie obvious to one of ordinary skill in the art to modify the teachings of Desai and Berner to obtain the features found in claims 213-215 as a matter of obvious design choice as they fail to patentably distinguish over the stated prior art.

21. As to claims 219, 241, 261, 319, Berner teaches evaluating whether values fall outside a predetermined range defined from a projected rate of change and/or acceleration (col. 21 lines 10-53).

22. As to claims 221, 243, 263, 321, Desai teaches replacing the values with a limit value ([0013]).

23. As to claims 222, 244, 264, 322, Desai teaches memory for storage ([0113]).

24. As to claim 258, Berner teaches comparing the rate of change with a preselected value (col. 21 lines 10-53).

25. Claims 154, 172, 187, 304, are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai (US 2003/0050546) in view of Berner (USP #6,233,471) as applied to claims 119 above, and further in view of Knobbe et al. (US 2002/0099282).

26. As to claim 154, 172, 187, 304, the above combination fails to teach the replacing step as claimed. However, Knobbe teaches a real-time glucose estimator

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using a recursive filter to output estimated glucose values (Abs). It would have been obvious to one of ordinary skill in the art to supplement the estimation taught by Desai and Berner with a recursive loop filter algorithm as taught by Knobbe for another means for estimating real-time glucose values for replacing signal errors.

27. Claims 224-226, 246-248, 266-269, 324-326 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai (US 2003/0050546) in view of Berner (USP #6,233,471) as applied to claims 119 above, and further in view of Mastrototaro (USP #6,424,847).

28. As to claims 224-225, 246-247, 266-267, 324-325, the above combination fails to teach the recited limitations of the claims. However, Mastrototaro teaches a maximum-average calculation where the maximum value for an interval is averaged with at least one maximum value associated with a previous interval (col. 8 line 67 to col. 9 line 2 – use of all data points for averaging include using the maximum values) to replace signal artifacts. As such, it would have been obvious to modify the above combination with Mastrototaro to use an established substitute to replacing signal artifacts.

29. As to claim 226, 268, Mastrototaro teaches that the interval comprises a time period (col. 2 lines 12-20).

30. As to claims 227, 248, 269, 326, Mastrototaro teaches the determination of a ratio and replacing the values if the ratio is outside a predetermined range (col. 12 lines 31-40).

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31. Claims 228-232, 249-253, and 327-331 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai (US 2003/0050546) in view of Berner (USP #6,233,471) as applied to claims 119 above, and further in view of Deutsch ("Time series analysis and control of blood glucose levels in diabetic patients").

32. As to claims 228, 249, 327, the combined teachings fail to teach the use of a time series analysis based on a variance of signal over a window of data. Deutsch teaches the use of time series analysis of blood glucose data to decompose data into clinically related components. As such, it would have been obvious to one of ordinary skill in the art to modify the combination to further incorporate the use of time series analysis as taught by Deutsch as a means for identifying patterns in time series data for higher accuracy in the interpretation of data.

33. As to claims 229-232, 250-253, and 328-331, the combined teachings fail to expressly teach a window of data at 15, 30, 45, and 60 minutes. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize a window of data at those specified minutes because the applicant has not disclosed that these specific time periods provide a particular advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the above combination to perform equally as well as applicant's as sampling can be done over any desired period of time. Therefore, it would have been prima facie obvious to modify the above combination to obtain the invention as specified in the above claims, because such a modification

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would have been considered a mere design consideration which fails to patentably distinguish over the stated prior arts.

Allowable Subject Matter

34. Claims 122, 192-207, 270-291, 293, 332-342 are allowed.

35. The following is a statement of reasons for the indication of allowable subject matter:

As to claim 122, the prior art of record fails to teach monitoring a data stream indicative of an output current and detecting a severity based in part on a frequency content of the signal artifact. While numerous teachings disclose the use of spectral analysis for filtering data or signal estimation, they do not teach its use in determining whether a signal should be replaced with estimated values based its the severity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon-Thurs (10-9:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

CJ
/C. J./
Examiner, Art Unit 3735
1/15/11